

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION**

UNITED STATES OF AMERICA)
)
v.) No. 2:19-00003
)
HEATHER L. MARKS)
HEMAL MEHTA, M.D.)
)

**MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS
SUPERSEDING INDICTMENT FOR LACK OF SUBJECT MATTER JURISDICTION**

Defendants Heather Marks, N.P., and Hemal Mehta, M.D., by and through their undersigned counsel, respectfully submit this Memorandum of Law in support of their jointly filed Motion to Dismiss the Superseding Indictment pursuant to Rule 12(b)(2) of the Federal Rules of Criminal Procedure.

I. Introduction and background

Hemal V. Mehta, M.D., and his co-defendant, Heather L. Marks, an Advanced Practice Registered Nurse, are charged with a series of federal drug trafficking crimes because the Government theorizes that they improperly prescribed pain medication to patients in a medical setting. In Count One, they are charged with intentionally and knowingly conspiring to distribute and dispense Schedule II controlled substances, including oxycodone and oxymorphone, without a legitimate medical purpose and outside the usual course of professional practice, from about September, 2016 through on or about May, 2018, in violation of 21 U.S.C. §846. (D.E. 40, Superseding Indictment, Count 1).

In addition to the overarching drug conspiracy, the Government has charged these medical professionals with nine substantive drug trafficking counts relating to specific patient

interactions. Counts Two through Ten allege that Dr. Mehta and Ms. Marks knowingly and intentionally dispensed and distributed oxycodone and oxymorphone, both Schedule II controlled substances, without a legitimate medical purpose and outside the usual course of professional practice on nine different dates to nine different patients, in violation of 21 U.S.C. §841(a)(1) and 18 U.S.C. §2 (D.E. 40, Superseding Indictment, Counts 2-10). The nine different dates range from December 22, 2016 through April 25, 2018.

Through its theory of prosecution set forth in the Superseding Indictment, the government admits that Dr. Mehta was a medical doctor and that he was properly licensed by the State of Tennessee Department of Health under license number 38517. His license was issued on March 2, 2004 and remained valid throughout the period alleged in the Superseding Indictment. The Government also acknowledges that, as part of his practice, Dr. Mehta prescribed controlled substances using his Drug Enforcement Administration (hereinafter “DEA”) license under DEA License Numbers (X)BM8730461 and FM7202360. (D.E. 40, PageID 88, ¶1-2).

The Government also concedes that Heather Marks, N.P., was licensed by the State of Tennessee Department of Health under license number 19885 on March 13, 2015 and that she prescribed controlled substances pursuant to authorization granted to her by DEA License Number MM3747562. (D.E. 40, PageID 88, ¶3-4). At all times relevant to the Superseding Indictment both licenses were in good standing.

In its simplest terms, because Dr. Mehta and Ms. Marks were properly licensed through all appropriate agencies to treat patients and prescribe scheduled narcotics at all relevant times, they were “authorized” to prescribe controlled substances pursuant to 21 U.S.C. §841(a). 21 U.S.C. §841(a) sets forth the “prohibited acts” covered by the Controlled Substances Act, in

relevant part, as follows:

- (a) Unlawful Act - *Except as authorized* by this subchapter, it shall be unlawful for any person knowingly or intentionally—
 - (1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance.

21 U.S.C. §841(a) (emphasis added).

However, the Government’s Superseding Indictment declares Dr. Mehta and Ms. Marks’ prescribing was “unlawful” by cross-referencing guidance outside the U.S. Code and, presumably supported at trial by having a well-paid, Government medical expert opine that the care rendered was not for a legitimate medical purpose (second guessing the medical practitioners in a treatment room with a patient) or within the “usual course of professional practice.” These Government imposed qualifying conditions on the definition of “authorized” are not codified in 21 U.S.C. §841. Yet, they are the linchpin of how the Government has managed to charge legitimate and duly licensed medical practitioners as drug traffickers.

In effect, the Superseding Indictment alleges that the “authorization” provided under 21 U.S.C. §841(a) to dispense or prescribe controlled substances is really a *conditional authorization*. That is, the authorization is *conditioned* on the distribution or dispensation of a controlled substance being for “a legitimate medical purpose” and within the “usual course of professional practice”, a condition that is not found within §841 nor anywhere else in the Controlled Substances Act in the context of medical professionals prescribing controlled substances. Rather, by relying on CFR § 1306.04 through permission conveyed by “*Chevron* deference” when a statute is ambiguous (a matter disputed by the defense) and under the Government’s theory and interpretation of the §841(a) language, a distribution or dispensation (presumably a prescription) becomes *automatically unauthorized* if it is made without a

“legitimate medical purpose and outside the usual course of professional practice.” In charging before the grand jury and at trial, the Government suggests that opinion testimony from a professional government medical expert (a “hired gun”) suffices to address whether the medical practitioner, charged as a criminal defendant, was operating a “legitimate medical practice” and thereby prove that the prescription was unauthorized, which, in turn, according to the Government (but not Congress) makes the act of prescribing “unlawful”. The Government’s circuitous logic and act of mental contortionism does not brand an otherwise lawfully licensed medical practitioner to be “unauthorized” to prescribe (distribute) under 21 U.S.C. §841. Only Congress has that authority.¹

For the reasons set forth in this memorandum, the conduct of Dr. Mehta and Ms. Marks was not “unlawful” under §841(a) because it was “authorized” at the time of prescribing according to the plain text of that statute and the admissions about their valid licensure set forth in the Superseding Indictment as set forth above. Therefore, the Superseding Indictment does not charge a cognizable federal offense.

Additionally, Dr. Mehta and Ms. Marks’s conduct was not “unlawful” pursuant to the plain and unambiguous text of §841(a) because: (1) the Attorney General lacked authority to

¹ As Justice Gorsuch wrote in his dissenting opinion in *Gundy v United States*, which Chief Justice Roberts joined:

The only real surprise is that the Court fails to make good on the consequences the government invited, resolving nothing and deferring everything. In a future case with a full panel, I remain hopeful that the Court may yet recognize that, while Congress can enlist considerable assistance from the executive branch in filling up details and finding facts, it may never hand off to the nation’s chief prosecutor the power to write his own criminal code. That “is delegation running riot.”

Gundy v. United States, 139 S. Ct. 2116, 2148, 204 L.Ed.2d 522, 556-57 (2019).

imply a *conditional* authorization to the §841(a) textual exception; (2) the Attorney General’s regulation (CFR § 1306.04) making the authorization *conditional* did not follow the Administrative Procedures Act rendering it null and void; and, (3) the Attorney General’s regulation does nothing more than “parrot” selected language from the Controlled Substances Act and adds no interpretive analysis to the statute and therefore deserves no deference whatsoever.

For all these reasons, the Government has failed to allege a cognizable federal crime against these “authorized” practitioners, and therefore, this Court lacks subject matter jurisdiction to hear this case.

II. Dismissal for lack of subject matter jurisdiction generally

Federal courts have subject-matter jurisdiction over prosecutions alleging violations of the federal criminal laws. 18 U.S.C. § 3231 (“The district courts of the United States shall have original jurisdiction, exclusive of the courts of the States, of all offenses against the laws of the United States.”). A “motion [asserting] that the court lacks jurisdiction may be made at any time while the case is pending.” Fed.R.Crim.P. 12(b)(2). According to the Sixth Circuit,

Lack of subject matter jurisdiction may be raised at any time in the course of a proceeding and is never waived. Matters of jurisdiction may be raised at any time, because if a court lacks subject matter jurisdiction, it does not have power to hear the case. Article III, Section 2 of the Constitution.

United States v. Adesida, 129 F.3d 846, 850 (6th Cir. 1997), *cert. denied*, 1998 U.S. LEXIS 3074 (May 4, 1998). Moreover, “federal courts have a duty to consider their subject matter jurisdiction in regard to every case and may raise the issue *sua sponte*.” *Answers in Genesis of Ky., Inc. v. Creation Ministries Int’l, Ltd.*, 556 F.3d 459, 465 (6th Cir. 2009).

The lack of subject matter jurisdiction to hear a criminal case includes when an

indictment does not actually charge a federal crime. “If an indictment does not charge a cognizable federal offense, then a federal court lacks jurisdiction to try a defendant for violation of the offense.” *Adesida*, 129 F.3d at 850 (citing *United States v. Armstrong*, 951 F.2d 626, 628 (5th Cir. 1992)). “If the government fails to plead conduct that is consistent with a violation of a criminal statute, the indictment or information is subject to dismissal for failure to state an offense.” *United States v. Tomahawk*, 2018 U.S. Dist. LEXIS 19820 (D.N.D. Feb. 7, 2018); See, also, *United States v. Bowling*, 2010 U.S. Dist. LEXIS 129708 (E.D. Ky. Dec. 7, 2010) (Defendant “could challenge the Court’s subject matter jurisdiction if the indictment charged something that *was not a crime...* ”) (*Id.*, at *4-5, italics in original)).

Because the Superseding Indictment filed against Dr. Mehta and Ms. Marks fails to allege a crime, the defendants move to dismiss the Superseding Indictment for lack of subject matter jurisdiction by this Court. The clear, unambiguous language of the Controlled Substances Act directs that, if a person is “authorized” to distribute or dispense controlled substances, their act of prescribing is not “unlawful”. The Controlled Substances Act gives the Attorney General *limited authority* over administering this authorization. Specifically, as discussed and analyzed more fully *infra*, the Attorney General’s authority is strictly limited to administering the registration process to make someone “authorized” (i.e., registering medical providers to prescribe scheduled controlled substances), to control under which schedule a substance is listed, and to administratively remove the authorization previously granted. It *does not* give the Attorney General *any* authority to dictate the practice of medicine, to define what is a “legitimate medical purpose”, or to circumvent the limitation of his authority through the criminal prosecutorial process. This issue can be resolved without introducing any evidence other than what the Government alleges as true in the Superseding Indictment about Dr. Mehta and Ms.

Marks' licensure and valid registration to prescribe and from applying the plain meaning of the text implemented by Congress in 21 U.S.C. §841.

III. Rules of statutory construction

“It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.” *Davis v. Michigan Dept. of Treasury*, 489 U. S. 803, 809 (1989).

Questions of statutory interpretation are reviewed under a three-step framework: first, a natural reading of the full text; second, the common-law meaning of the statutory terms; and finally, consideration of the statutory and legislative history for guidance. *United States v. Wright*, 774 F. 3d 1085, 1088 (6th Cir. 2014) (citing *Elgharib v. Napolitano*, 600 F.3d 597, 601 (6th Cir.2010)). The natural reading of the full text requires that a court examine the statute for its plain meaning, including the language and design of the statute as a whole. If the statutory language is not clear, a court may examine the relevant legislative history. *Id.* If a statutory term is undefined, a court should apply its ordinary meaning. *United States v. Santos*, 553 U.S. 507, 511 (2008). “As in all cases of statutory construction, [a Court’s] task is to interpret the words of [the statute] in light of the purposes Congress sought to serve.” *Dickerson v. New Banner Inst., Inc.*, 460 U.S. 103, 118 (1983) (quoting *Chapman v. Houston Welfare Rights Org.*, 441 U.S. 600, 608 (1979)).

IV. The Controlled Substances Act

The Comprehensive Drug Abuse Prevention and Control Act of 1970 is a huge and complex piece of legislation. The Controlled Substances Act (hereinafter “CSA”) is found under Title II of the Drug Abuse Prevention and Control Act and can be found in its entirety via the DEA’s website, <https://www.dea.gov/drug-information/csa>. That hyperlink will then redirect to

<https://uscode.house.gov> where one can select which version of the CSA is displayed as it has been amended several times over the last few years.² Because the Superseding Indictment alleges that the conduct occurred between September, 2016 to May, 2018, the 2012 Edition with Supplement V (1/12/2018)³ of the CSA will be used.⁴

It is useful to look at the entire CSA as an Act for the purpose of searching for terms that appear throughout. In this instance, we look for the terms “valid prescription”, “legitimate medical purpose”, and “in the usual course of his professional practice”, terms used by the Attorney General in 21 C.F.R. § 1300, *et seq.*, which is the primary source of the Government’s claim of prosecutorial authority, to see if Congress used those terms and the context surrounding their use in the text of the Act.⁵

A. Other appearances of the term “Valid prescription” in the CSA

The first appearance of the term “valid prescription” is found in §802 (Definitions),

² See,

<https://uscode.house.gov/view.xhtml?hl=false&edition=2018&req=granuleid%3AUSC-2018-title21&num=0&saved=%7CZ3JhbnVsZWlkOlVTQy1wcmVsaW0tdGl0bGUyMS1zZWN0aW9uODAx%7C%7C%7C0%7Cfalse%7Cprelim> (last visited March 10, 2024).

³ The Superseding Indictment (D.E. 40) alleges a conspiracy from “September 2016, through on or about May 2018” and individual dispersements from December 22, 2016 (Count 2) through April 25, 2018 (Count 10). These dates encompass different versions of the CSA but, for purposes of this memorandum only, the 2012 Edition with Supplement V (1/12/2018) encompasses the alleged dates and any difference do not affect the legal points raised in this memorandum. (The next version would be 2018 Main Edition (1/14/2019) which would raise a potential *ex post facto* issue.) Therefore, all references to the CSA will be to the 2012 Edition with Supplement V (1/12/2018).

⁴ Title II of the Drug Abuse Prevention and Control Act, Part A, §100 states that this title “may be cited as the ‘Controlled Substances Act’.” See, Title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, as amended. It is codified under Title 21, United States Code, §801, *et seq.*, and the section numbers in the Code track the section numbers in the Act itself.

⁵ 21 U.S.C. § 1306.04 is specifically cited in the Superseding Indictment as the basis for making the alleged conduct unlawful. (D.E. 40, ¶5, PageID 88 (“Under the Controlled Substances Act, Title 21, United States Code, Section 841(a) *et seq.*, and Title 21, Code of Federal Regulations, Section 1306.04, a prescription for a controlled substance is not legal or effective unless issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.”). Defendants argue here that this is a misstatement of the law.

subsection (55). However, the term “valid prescription” is used in defining the “term ‘refilling prescriptions for controlled substances in Schedule III, IV, or V’” and limits it to a “valid prescription that meets the requirements of subsection (b) and (c) of section 829 of this title...”

Importantly, Dr. Mehta and Ms. Marks are charged with dispensing only Schedule II substances. (See, D.E. 40, Superseding Indictment, describing “oxycodone and oxymorphone” as “Schedule II controlled substances”). So, the reference to “valid prescription” found in §802(55) cannot apply because it is limited to “refilling prescriptions for controlled substances in Schedule III, IV, or V.”

For the sake of completeness though, §802 cross-references §829(b) and (c). 21 U.S.C. §829(b) reads:

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.301 et seq.], may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act [21 U.S.C.353(b)]. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

21 U.S.C. §353(b), in turn, says that a

drug intended for use by man which – (A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or (B) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug; shall be dispensed only (I) upon a written prescription of a practitioner licensed by law to administer such drug ...

Thus, it appears neither §829(b), nor §353(b), really define the term “valid prescription”.

21 U.S.C. § 829(c) (titled “Schedule V substances”) states that “no controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.” Again, this subsection does not really define the term “valid prescription” in the context of Schedule II controlled substances prescribed by a medical practitioners.

In the context of 21 U.S.C. §829(e) (titled “Controlled substances dispensed by means of the Internet”), the statute states:

- (2) As used in this subsection:
 - (A) The term “valid prescription” means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—
 - (i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or
 - (ii) a covering practitioner.”

However, Congress clarifies that definition only applies to “this subsection” expressly dealing only with “[c]ontrolled substances dispensed by means of the internet.” There is no allegation that Dr. Mehta or Ms. Marks dispensed or prescribed any controlled substances via the internet. They are not charged under this provision. Thus, this definition is inapplicable to their alleged conduct.

The next reference to “valid prescription” is found in §830 titled “[r]egulation of listed chemicals and certain machines.” Section 830(b)(3)(A)(ii) states that, in the context of “mail order reporting” of “regulated transaction[s] involving a listed chemical, a tabletting machine, or an encapsulating machine”, “the “term ‘valid prescription’ means a prescription which is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner’s professional practice.” Again, we are left without a definition of “valid prescription” in the context of a medical practitioner prescribing a Schedule II controlled substance.

In short, there is no definition for the term “valid prescription” in the Controlled Substances Act as it relates to a Schedule II controlled substance dispensed by a medical practitioner to his or her patient.

B. Legitimate medical purpose and usual course of his professional practice

Section 802 defines a “practitioner” as a physician licensed by the jurisdiction in which he practices to dispense a controlled substance in the “course of professional practice or research.” Noticeably absent from this definition of “practitioner” is the phrase “legitimate medical purpose”. In fact, that phrase does not appear until §830 (titled “regulation of listed chemicals and certain machines” and clearly applicable to the manufacturing process) where the term “valid prescription” is defined as “a prescription which is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice.” However, this definition is only applicable to “this paragraph” or to the reports required to be made to the Attorney General every two years relating to the regulation of pill making machines and chemical compounds used in manufacturing controlled substances. 21 U.S.C. §830(b)(3)(A)(ii). So, yet again, the definition in §830 does not apply to Dr. Mehta's or Ms. Marks' alleged conduct.

C. Statutorily guiding language of Section 841 defining who may be prosecuted - “Except as authorized”

Section 841(a), titled “unlawful acts”, states:

[e]xcept as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally – (1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance ...

21 U.S.C. §841(a) (emphasis added). Of paramount importance is the complete absence of any

mention of a *conditional* authorization. In other words, the “as authorized” language does not read “as authorized *if* the distribution is for a legitimate medical purpose” or “as authorized *if* the distribution is within the usual course of professional practice” or “as authorized *if* distributed within the standard of care”. To put it succinctly, there is no *conditional* authorization. One is either “authorized” to distribute controlled substances or one is not. Authorization is created by valid licensure and registration to prescribe scheduled controlled substances. To read a *conditional* authorization – that is, an authorization that is conditioned on being for a legitimate medical purpose as that term is defined by guidelines or by a Government expert – is to read into the statute a requirement that is simply not there.

Just as important is the complete absence of any definition of “authorized” or “except as authorized” being tied to a standard of care, to a legitimate medical purpose, or to the idea of a course of professional practice. Indeed, within the entire Controlled Substances Act, the term “authorized” and the phrase “except as authorized” is never defined.⁶ If the Attorney General, the Department of Justice, or any federal court, reads into the word “authorized” as being *conditioned* on the distribution being for a legitimate medical purpose or within the usual course of professional practice, then they are inserting text into the statute that was not crafted by Congress.⁷

⁶ This is so even though the term “except as authorized” appears a total of six times in the Controlled Substances Act. See, §841(a), §841(c)(1) and (2) (offenses involving listed chemicals), §841(h)(1)(A) (offenses involving dispensing of controlled substances by means of the Internet), §856(a)(1) (maintaining drug-involved premises), and §861(f) (Distribution of controlled substance to pregnant individual).

⁷ Yet, that is exactly what courts have routinely done. And that is exactly what the Sixth Circuit Pattern Jury Instructions have done. To wit: “The defendant’s dispensing was unauthorized, that is to say the dispensing was not for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice”. (6th Circuit PJI 14.02C). In effect, this element purports to redefine the word “authorized” found in §841(a) by stating it in the negative and *conditioning* the

Because the added *condition* to being “authorized” is rooted and derived from a regulation, that is 21 C.F.R. § 1306.04, and not from the text of the statute itself, it is important to examine if the Attorney General even had authority to *condition* the “except as authorized” phrase found in §841(a). Indeed, if the Attorney General lacked authority to change the language of §841(a) by adding a *condition* to whether one is “authorized”, then as long as one is “authorized” to distribute or dispense, the conduct cannot be “unlawful” under §841(a). And if the alleged conduct cannot be unlawful, then this Court lacks subject matter jurisdiction to adjudicate the case and must dismiss this prosecution.

D. Becoming “authorized” and the authority of the Attorney General to deem one “unauthorized” by regulation.

The Controlled Substances Act does not actually state specifically how one becomes “authorized” or who has authority to “authorize” someone to distribute or dispense a controlled substance, but the Act does describe the “registration” process throughout.

Section 823(b) reads,⁸

authorization on whether it was made for a legitimate medical purpose by an individual acting in the usual course of his professional practice. But, as argued here, this language or condition is *not* in the Controlled Substances Act and is completely fabricated by the Government and until now, embraced by the Courts. Where does the Sixth Circuit Pattern Jury Instruction Committee find authority in support of this PJI? Certainly not from the CSA, but rather from a regulation, 21 C.F.R. § 1306.04. See, Committee Commentary to 14.02C. See, also, Superseding Indictment, D.E. 40, ¶5. Indeed, in supporting the language of 14.02C, ¶(1)(C), the Committee conspicuously omits reference to the CSA itself as support. (*Id.*) But as we argue, the Attorney General had no authority to rewrite ¶841(a) by inserting a *condition* to the authorization and neither does this Court.

The PJI Committee goes on to define the *conditional* phrase “legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice” as “acting in accordance with generally recognized and accepted standards of that individual’s professional practice.” Importantly, the committee concedes that “**standards for the different kinds of professional practice are set by various organizations. The law applicable to this offense does not define this phrase further.**” In other words, the Committee completely failed to cite to any authority for this definition and essentially concedes that the elements for prosecuting a physician vary depending on the “kind[] of professional practice”.

⁸ Reference is only to subsection (b) because it deals with Schedule II drugs and

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

- (1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;
- (2) compliance with applicable State and local law;
- (3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
- (4) past experience in the distribution of controlled substances; and
- (5) such other factors as may be relevant to and consistent with the public health and safety.

Because §841(a) refers to distribution and §823(b) refers to registering an applicant to distribute, it is a reasonable reading of the Act as a whole to conclude that the Attorney General of the United States has authority to “register” applicants who wish to distribute controlled substances after considering whether the registration of the applicant is consistent with the public interest.

Further, the Attorney General is given authority to make rules and regulations relating to this registration process. Section 821 says the **“Attorney General”** is authorized to promulgate rules and regulations … relating to regulation and control of the … dispensing of controlled substances ….” and may charge fees for registration (emphasis added). Section 822, in turn, says every “person who … distributes any controlled substance …, or who proposes to engage in the

Defendants are only charged with dispensing and distributing Schedule II drugs. The other subsections of §823 deal with the manufacture of controlled substances (Defendants are not charged with

... distribution of any controlled substance ..., shall obtain annually a registration issued by the **Attorney General** in accordance with the rules and regulations promulgated by him" (emphasis added). In short, the **Attorney General** of the United States, who "leads the Justice Department" is authorized by Congress to make rules regulating and controlling the dispensing of controlled substances and the registration of those authorized to dispense, including the "except as authorized" part of §841(a).⁹

It is undisputed that the Attorney General has the authority to issue regulations about controlled substances (a) because §823(b) gives the Attorney General direct authority to register applicants wanting to distribute controlled substances and (b) because §822 directs applicants to obtain registration from the Attorney General in accordance with rules and regulations promulgated by him and, finally, (c) because §821 give the Attorney General direct authority to promulgate rules and regulations relating to regulation and control of the dispensing of controlled substances. This point is not in dispute. However, that authority is strictly limited by statute. Congress expressly directs in the CSA that the Attorney General can promulgate rules and regulations relating to the "control" of the dispensing of controlled substances.

At face value, "control" would seem to give the Attorney General authority to control the dispensing of controlled substances by any regulations he deems fit to issue, including 21 C.F.R. § 1306.04, the operative regulation in this context, that sets a *condition* to the term "as authorized". But Congress clarified what it meant by "control". 21 U.S.C. 802(5) directs that "control", as "used in this subchapter" (that is, "Control and Enforcement", which includes §821 and §841) means "to add a drug or other substance, or immediate precursor, to a schedule under

manufacturing) or deal with drugs in other schedules.

⁹ This is the same Attorney General that is the head of the Department now prosecuting

Part B of this subchapter, whether by transfer from another schedule or otherwise.” Put another way, the Attorney General has authority to issue regulations relating to the “registration” of those “authorized” to distribute controlled substances and to “control” the distribution by adding a drug to a schedule as defined elsewhere in the CSA. (See, also, Part B – Authority to Control; Standards and Schedules, §811, giving the Attorney General authority to make rules and regulations to “add to such schedule or transfer between such schedules...”)

Nowhere in the CSA or elsewhere did Congress give the Attorney General authority to issue a regulation mandating that a prescription is “effective” if given for a “legitimate medical purpose in the usual course of his professional practice”. (See, 21 C.F.R. § 1306.04)¹⁰ Also, *nowhere* did Congress give the Attorney General the authority to say what a legitimate medical purpose is by adopting or referring to the Federation of State Medical Boards (FSMB) Model Policy, CDC Guidelines or anything else. Nor can the Attorney General, through the Department of Justice, through a DOJ Trial Attorney, define the phrase (as authorized) through some professional witness charading as an expert based on his personal training and experience in medicine and make it a criminal act if a medical practitioner does not follow what some guideline recommends, or some obscure expert opines is proper.

The limited authority to make rules and regulations related to registration is further

Defendants.

¹⁰ Interestingly, the Attorney General cites to “21 U.S.C. 821, 823, 829, 829a, 831, 871(b) unless otherwise noted” as “[a]uthority” for issuing Regulations in “Part 1306-Prescriptions”, including § 1306.04 defining what an “effective” prescription is and redefining the §841(a) authorization to be conditioned on that prescription being issued for a “legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice” and that anyone knowingly issuing such a prescription “shall be subject to the penalties provided for violations of the provisions of law related to controlled substances.” See, <https://www.ecfr.gov/current/title-21/chapter-II/part-1306>. Yet, none of those cited sections of the Controlled Substances Act gives him authority to make §841(a) authorization *conditional* nor the authority to make it a criminal act if one does not abide by his regulation. He has authority on an administrative front only.

limited by Congress through the text of the Controlled Substances Act. Section 824 deals with the process for revoking or suspending the registration. It reads:

(a) Grounds

A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

- (1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II;
- (2) has been convicted of a felony under this subchapter or subchapter II or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;
- (3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;
- (4) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section; or
- (5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a-7(a) of title 42.

A registration pursuant to section 823(g)(1) of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(g)(1) of this title.

(b) Limits of revocation or suspension

The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

(c) Service of show cause order; proceedings

(1) Before taking action pursuant to this section, or pursuant to a denial of registration under section 823 of this title, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended.

(2) An order to show cause under paragraph (1) shall—

(A) contain a statement of the basis for the denial, revocation, or suspension, including specific citations to any laws or regulations alleged to be violated by the applicant or registrant;

(B) direct the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but not less than 30 days after the date of receipt of the order; and

(C) notify the applicant or registrant of the opportunity to submit a corrective action plan on or before the date of appearance.

(3) Upon review of any corrective action plan submitted by an applicant or registrant pursuant to paragraph (2), the Attorney General shall determine whether denial, revocation, or suspension proceedings should be discontinued, or deferred for the purposes of modification, amendment, or clarification to such plan.

(4) Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this subchapter or any other law of the United States.

(5) The requirements of this subsection shall not apply to the issuance of an immediate suspension order under subsection(d).

Section 824 plainly delineates the scope of the Attorney General's authority in this context. The Attorney General has limited authority to revoke or suspend a medical provider's registration *after* he or she has complied with certain, very specific, administrative procedures. Again, *nowhere* did Congress give the Attorney General authority to *criminalize* the conduct of a

medical practitioner who is “authorized” to distribute controlled substances. Rather, Congress dictated a very specific administrative remedy and process to suspend or revoke that registration and authorization.

V. The Attorney General Regulations (CFRs)

The Attorney General, presumably under the authority of §821 as conferred by Congress, promulgated some regulations codified in Title 21 CFR, Chapter II, Drug Enforcement Administration, Department of Justice.¹¹ As a threshold matter, the definitions promulgated by the Attorney General are found at 21 CFR § 1300. Section 1300.01 deals with definitions “relating to controlled substances”. Relevant to this motion are the following definitions:

1. Dispenser is defined as “an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance.”
2. Individual practitioner is defined as “a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.”
3. Prescription is defined as “an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user ...”

21 CFR § 1300.

¹¹ The Code of Federal Regulations (CFR) is a compilation of general and permanent rules published in the *Federal Register* by the executive (not legislative) branch of the Federal Government. It is drafted by executive departments and agencies within the government and published annually relating to the administration of government.

There is no definition for “valid prescription” or reference to “legitimate medical purpose”. While an introductory catch-all definition refers back to 21 U.S.C. §802 (“Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) ...”), §802 does not define the term “valid prescription” or the phrases “legitimate medical purpose” or “in the usual course of professional practice”.

21 CFR § 1300.03 provides definitions for various terms “relating to electronic orders for controlled substances and electronic prescriptions for controlled substances.” There, we find the first definition of “valid prescription” by the Attorney General that mentions the term “legitimate medical purpose”. According to the Attorney General (not Congress), “valid prescription means a prescription that is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice.” However, this term is defined only relating to “electronic prescriptions for controlled substances”. Again, there is no allegation that Dr. Mehta or Ms. Marks prescribed by “electronic” means. But even if either did, the terms “issued for a legitimate medical purpose” and “in the usual course of the practitioner's professional practice” remain completely undefined by Congress or the Attorney General.

Finally, we must examine 21 CFR § 1306.04 dealing with the “Purpose of issue of prescription” [sic], the regulation the United States relies upon to prosecute doctors and other medical practitioners for prescribing to patients. There, the regulation states that a “prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 CFR §

1306.04(a).¹² It further states that an

order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Two points are particularly noteworthy relating to this regulation. First, the latter part of § 1306.04(a) uses the term “in the usual course of professional *treatment*” instead of “in the usual course of professional *practice*” as used in the first part of the regulation and in 21 U.S.C. §829(e). Second, this CFR makes a reference to “the meaning and intent” of §829. No explanation is given as to the change from “practice” to “treatment” nor are those words or phrases further defined. Second, the reference to the “meaning and intent of 309 of the Act (21 U.S.C. 829)” must refer to the section of 829 that deals with “prescriptions” or “valid prescriptions”. As explained above, the *only* references in §829 to “prescriptions” or “valid prescriptions” is in the context of, and limited to, those prescriptions dispensed via “the Internet”. See, 21 U.S.C. §829(e). Again, these practitioners did not dispense any prescriptions to a patient via “the Internet”.

It remains, then, that neither Congress nor the Attorney General have ever defined the terms “in the course of professional practice”, “usual course of the practitioner's professional practice”, “in the usual course of professional treatment”, “legitimate medical purpose”, or any derivation thereof. Even the term “valid prescription” remains undefined in relation to the context in which Dr. Mehta and Ms. Marks are charged.

So, how can a branch of the Department of Justice headed by the Attorney General

¹² The term “effective” is not defined.

attempt to get around this definitional black hole and complete lack of well-defined and logically delineated regulations regarding the “except as authorized” language of §841(a)? The Government attempts to plug this gaping hole by crafting an arbitrary standard so it can prosecute doctors and other medical providers as drug dealers and then by having experts testify about a generalized “standard of care” (a process rejected by *Ruan v United States*, 142 S.Ct. 2370 (2022)) and who mostly apply guidelines promulgated by the CDC or other various state agencies and even private institutions.¹³ These experts also attempt to introduce the standard of care based on their own individual medical school “training and experience” and critique record keeping, robustness of physical exams, so-called “red flags”, distance traveled by patients, whether cash is accepted as payment, how many patients are on pain medications, etc. – *none of which is criminal*. These experts even purport to conclude that certain conduct is not “in the course of professional practice” or for a “legitimate medical purpose” because they disagree with the practitioner who was in the examination room with the patient.¹⁴ But the CDC is part of the Department of Health and Human Services (HHS), not the Department of Justice headed by the Attorney General.¹⁵ In fact, trying to define those terms through so-called experts who use non-DOJ “guidelines” further violates the Administrative Procedures Act, specifically 5 U.S.C. §553, which requires “rule making” to first be published in the Federal Register followed by a public

¹³ See, *Ruan* at 2381 (rejecting the Government's proposed standard of “objectively reasonable good-faith effort” as turning a “defendant's criminal liability on the mental state of a hypothetical “reasonable” doctor, not on the mental state of the defendant himself or herself” and would require a physician to “conform his conduct to something that his fellow doctors would view as medical care”.

¹⁴ None of these experts have ever pointed to where the Attorney General has defined those terms and merely come up with their own conclusions about what those phrases mean.

¹⁵ See,
https://www.cdc.gov/about/organization/cio.htm?CDC_AA_refVal=https%3A%2Fwww.cdc.gov%2Fabout%2Forganization%2Findex.html (stating that CDC is “one of the major operating components of

comment period. The Attorney General has never proposed any rule or regulation that define “valid prescription”, “course of professional practice”, “course of professional treatment”, or “legitimate medical purpose” that was submitted to public comment in compliance with the APA. See discussion *infra*.

VI. The Attorney General exceeded his authority by dictating what an effective prescription was which runs afoul of *Gonzales v Oregon*, 546 U.S. 243 (2006)

As discussed *supra*, 21 U.S.C. §841(a) says “except as authorized”, it is unlawful to distribute, disperse, etc. controlled substances. It is undisputed that §821 gives the Attorney General authority to “promulgate rules and regulations relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances....” where “registration” means the process and procedure of registering and the fees to be charged.

“Control”, however, simply means to “to add a drug or other substance” to a particular Schedule. Put another way, the Attorney General has authority to issue regulations relating to the “registration” of those “authorized” to distribute controlled substances and to “control” the distribution by adding a drug to a schedule as defined elsewhere in the CSA.

The United States Supreme court in *Gonzales v Oregon*, 546 U.S. 243 (2006) says as much. There, the Attorney General issued an “interpretive ruling” stating if a doctor prescribes a controlled substance for the purpose of assisting a suicide, then that prescribing was not for a “legitimate medical purpose”, and it would be unlawful.¹⁶ The U.S. Supreme Court declared the Attorney General exceeded his “limited authority”.

the Department of Health and Human Services.”)

¹⁶ This is really no different than the Attorney General, through 21 C.F.R. § 1306.04, telling medical providers that if they prescribe a controlled substance without a “legitimate medical purpose” as defined by a particular unnamed guideline or by an obscure former-addict doctor, then the distribution will be deemed unlawful.

The Attorney General has rulemaking power to fulfill his duties under the CSA. The specific respects in which he is authorized to make rules, however, instruct us that he is not authorized to make a rule declaring illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law.

Id., at 258. Also, the “statutory references to ‘control’ outside the scheduling context make clear that the Attorney General can establish controls ‘against diversion,’ e.g., § 823(a)(1), but do not give him authority to define diversion based on his view of legitimate medical practice.” *Id.*

If the Attorney General cannot issue a regulation that says prescribing for the purpose of assisting suicide is not a “legitimate medical purpose” and therefore unlawful and subject to prosecution, then it reasons that the Attorney General cannot say that prescribing where “red flags” are present is “without a legitimate medical purpose” and therefore unlawful. *Gonzales* is directly on point and persuasive authority, standing for the clear rule that the practice of medicine and the definition of what is legitimate medicine is for the states to decide, not the federal executive branch.

In this case, the United States via the Superseding Indictment alleges that Dr. Mehta’s and Ms. Marks’ prescribing in the particular instances were not for a “legitimate medical purpose” and were, therefore, a criminal act. The Government intends to define “legitimate medical purpose” (a criteria it inappropriately grafts onto the statute to criminalize a medical practitioner’s prescribing) through references to “guidelines” issued by other agencies, such as the Centers for Disease Control, or through private entities, such as the Federation of State Medical Boards (FSMB), or through the opinion of an obscure, former-addict, doctor. Yet, as argued herein, the Controlled Substances Act does not give the Government authority to define what is a “legitimate medical purpose” (which is tantamount to federalizing the definition of practicing medicine). Nor does the CSA give the Government authority to criminalize conduct

that is “authorized” via the registration process. The only authority the CSA gives to the Government is to undergo the process of suspending or revoking that authorization through an administrative process. *If, and only if, and only after*, such registration is suspended or revoked, does the act of distributing a controlled substance become “unauthorized”. Then, when the “except as authorized” language of §841(a) is removed, the act of distribution becomes “unlawful”. If the government wishes to pursue administrative remedies to address Dr. Mehta and Ms. Marks’ registration, they are authorized to implement that administrative process. What the Government is not authorized to do is prosecute medical professionals as if they are drug dealers under 21 U.S.C. §841 when they are, in fact, prescribing medication to real patients pursuant to valid licensure granting them “authorization”.

By criminalizing conduct that is “authorized” through the registration process and exempted from being “unlawful” and when such registration has not been suspended or revoked, the Government is circumventing the plain text and reading of the Controlled Substances Act. The CSA even provides for an emergency suspension by the Attorney General “simultaneously with the institution of proceedings” where he “finds that there is an imminent danger to the public health or safety.” §824(d). Such emergency suspension even remains “in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.”

But rather than proceed through this Congressionally mandated administrative suspension process, the Attorney General instead expends enormous resources to build evidence to use in a future prosecution all while allowing a registered and authorized physician to continue doing

exactly what the Government claims is unlawful conduct.¹⁷

Dr. Mehta and Ms. Marks were authorized to prescribe under the CSA. They cannot be prosecuted because the Government has crafted additional requirements not set forth or ratified by Congress. The Attorney General is not authorized to craft its own definitions and then prosecute medical professionals under its subjective and largely arbitrary standard. Because medical professionals who are duly licensed are “authorized” to prescribe under the CSA, their act of prescribing to patients in a medical context cannot be unlawful. For these reasons, the Superseding Indictment fails to allege a crime, and this Court lacks subject matter jurisdiction. This case should be dismissed.

VII. Even assuming *arguendo* that the Attorney General had such authority, he did not comply with the Administrative Procedures Act in crafting the definition of “legitimate medical purpose” via guidelines or medical experts in a criminal proceeding.

The Administrative Procedures Act (APA) “sets forth the procedures by which federal agencies are accountable to the public and their actions subject to review by the courts.” *Franklin v. Massachusetts*, 505 U.S. 788, 796 (1992). It requires agencies to engage in “reasoned decision-making,” *Michigan v. EPA*, 576 U.S. 743, 750 (2015) (internal quotation marks omitted) and directs that agency actions be “set aside” if they are “arbitrary” or “capricious,” 5 U.S.C. § 706(2)(A).

In *Paulsen v. Daniels*, 413 F.3d 999 (9th Cir. 2005), the Court of Appeals considered whether the Bureau of Prisons violated the Administrative Procedure Act in adopting an interim regulation pertaining to an early release incentive program for federal prisoners who had

¹⁷ The Government sends undercover agents into medical clinics hoping to bait medical providers into prescribing to fake pill seekers. The undercover attempts to manufacture so-called “red flags”. Never mind that “red flags” are not discussed anywhere in the CSA or the CFR.

successfully completed a substance abuse program (commonly referred to as RDAP). Congress had required the BOP to “make available appropriate substance abuse treatment for each prisoner the Bureau determines has a treatable condition of substance addiction or abuse.” Crime Control Act of 1990, Pub. L. 101-647, § 2903, 104 Stat. 4789, 4913 (codified as amended at 18 U.S.C. § 3621(b)). As an incentive for prisoners to participate, Congress allowed the BOP to reduce a sentence up to one year for prisoners convicted of “nonviolent offense[s]” and who completed the RDAP curriculum. Violent Crime Control and Law Enforcement Act of 1994, Pub. L. 103-322, § 32001, 108 Stat. 1796, 1897 (codified at 18 U.S.C. § 3621(e)(2)(B)). The BOP issued a regulation that defined “nonviolent” as excluding those who had been convicted of firearm offenses by relying on the definition of “crime of violence” found in 18 U.S.C. §924(c)(3), including firearms offenses under 18 U.S.C. 922(g) and offenses under 21 U.S.C. 841(a) which included a guidelines-based firearms enhancement. Because of a circuit split on the issue of whether the BOP had authority to exclude these offenses from the definition of “nonviolent” offenses, the BOP issued an interim regulation in 1997 again excluding firearm offenses from the list of eligible convictions. In support and instead of relying on the “crime of violence” definition in §924(c), the BOP relied on “the discretion allotted to the Director of the Bureau of Prisons in granting a sentence reduction to exclude [enumerated categories of] inmates rather than defining the statutory terms ‘prisoner convicted of a nonviolent offense’ or ‘crime of violence.’” *Paulsen*, at 1003. In short, the BOP bypassed the dispute on its power to *define* “nonviolent offenses” and circumvented the controversy by citing to the general “discretion” given to the BOP.

The Ninth Circuit concluded that the BOP “plainly violated the APA in its promulgation of the 1997 interim regulation.” *Paulsen*, at 1004.

The APA requires agencies to follow certain procedures

when it decides to issue a rule, including: (1) publishing notice of the proposed rule-making in the Federal Register, 5 U.S.C. § 553(b); (2) providing a period for interested persons to comment on the proposed rule, which comments will be considered by the agency prior to adopting the rule, *id.* at § 553(c); and (3) publishing the adopted rule not less than thirty days before its effective date, with certain exceptions that are not applicable here, *id.* at § 553(d).

“In enacting the APA, Congress made a judgment that notions of fairness and informed administrative decisionmaking require that agency decisions be made only after affording interested persons notice and an opportunity to comment.”

Chrysler Corp. v. Brown, 441 U.S. 281, 316, 60 L. Ed. 2d 208, 99 S. Ct. 1705 (1979); see also *Riverbend Farms, Inc. v. Madigan*, 958 F.2d 1479, 1485 (9th Cir. 1992) (“The notice and comment requirements . . . are designed to ensure public participation in rulemaking.”). It is antithetical to the structure and purpose of the APA for an agency to implement a rule first, and then seek comment later. The district court correctly concluded that the Bureau violated § 553(b) and (d).

Id., at 1004-05. The Ninth Circuit, noting that “[o]rdinarily when a regulation is not promulgated in compliance with the APA, the regulation is invalid”, affirmed the district court below which had invalidated the rule on initial review.

In *Arrington v Daniels*, 516 F.3d 1106 (9th Cir. 2008), the Court was again asked to review a regulation by the BOP on the same issue that was “identical to the 1997 interim rule”. The question presented was, again, whether the Bureau of Prisons violated Section 706(2)(A) of the Administrative Procedure Act when it promulgated the new, revised, regulation. The Court concluded that it had. Once again, the BOP attempted to circumvent the dispute over whether it had authority to “define” what a “nonviolent offense” meant and instead relied on the general “discretion allotted to the Director...” *Id.*, at 1111. Petitioners argued that this was not enough and that the BOP had to provide a rationale explaining the decision to categorically exclude certain prisoners. Failure to provide this rationale made the regulation arbitrary and capricious in

violation of the APA. The Ninth Circuit agreed, holding that “[b]ecause we find that the administrative record contains no rationale explaining the Bureau’s decision to categorically exclude prisoners with convictions involving firearms from eligibility for early release under § 3621(e), we reverse.” *Id.*, at 1112.

Here, the Attorney General failed to proceed through the notice and comment rule-making process when it crafted definitions to graft onto 21 U.S.C. §841 (as described above), which the Administrative Procedure Act requires before an agency’s regulation can “have the force and effect of law.” *Perez v. Mortgage Bankers Assn.*, 575 U.S. 92, 96 (2015) (internal quotation marks omitted); see, also, 5 U.S.C. §553. “Unless a statutory exception applies, the APA requires agencies to publish a notice of proposed rulemaking in the Federal Register before promulgating a rule that has legal force.” *Little Sisters Poor Saints Peter Paul Home v PA*, 140 S.Ct. 2367, 2384 (2020) (citing 5 U.S.C. §553(b)). “Aside from these notice requirements, the APA mandates that agencies ‘give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments’”. *Id.*, at 2386.

The Attorney General has never submitted any proposed rules or regulations that clearly state the “except as authorized” provision of §841(a) is *conditioned* on the Attorney General’s opinion of what is a “legitimate medical purpose”. Nor has the Attorney General ever submitted any proposed rules in the Federal Register defining the terms “in the course of professional practice” or “legitimate medical purpose” in clear terms so that physicians and others have an unambiguous understanding of conduct that would be deemed unlawful and criminal and had an opportunity to comment on a proposed rule. To be sure, 21 CFR § 1306.04 does use those terms, but they are not further defined and the regulation is merely “parroting” terms used by Congress. *Gonzales v Oregon*, 546 U.S. 243, 257 (2006). This regulation, § 1306.04, “does little more than

restate the terms of the statute itself. The language ... comes from Congress, not the Attorney General, and the near equivalence of the statute and regulation belies the Government's argument for *Auer* deference." *Id.*, at 257 (2006) (citing to *Auer v Robbins*, 519 U.S. 452, 461-463 (1997) (holding that an administrative rule may receive substantial deference if it interprets the issuing agency's own ambiguous regulation.)) "An agency does not acquire special authority to interpret its own words when, instead of using its expertise and experience to formulate a regulation, it has elected merely to paraphrase the statutory language." *Id.*

Essentially, what the Attorney General has done in these medical provider cases, is overstep a clear limitation on its authority to promulgate rules and regulations by drafting a rule that merely parrots the statutory language and *conditioning* the authorization referred to in §841(a) on what he thinks is legitimate medical practice, leaving that term undefined and ambiguous. Then, to fill in the gap on the undefined term "legitimate medical purpose", the Attorney General turns to the prosecutorial realm to define that term through the testimony of a purported expert who, in turn, merely "parrots" language from a variety of "guidelines" on opioid prescribing. However, these guidelines claiming to define what is a legitimate medical practice, were *never submitted for public comment via the APA process*. Nor has the Attorney General ever published a rationale for relying on CDC Guidelines, FSMB Guidelines, or any other external source for defining what "legitimate medical purpose" even means. Indeed, if that term is defined by "accepted standards of that individual's professional practice", as the Sixth Circuit Pattern Jury Instruction Committee states, then where are these standards published? If the Attorney General is going to rely on "accepted standards of that individual's professional practice" to define "legitimate medical purpose", then those standards must be published in the Federal Register and be open to public comment before becoming final.

Indeed, the Supreme Court in *Gonzales* practically invited the Attorney General to fill the void.

All would agree, we should think, that the statutory phrase **‘legitimate medical purpose’ is a generality, susceptible to more precise definition and open to varying constructions, and thus ambiguous in the relevant sense....** To begin with, the rule must be promulgated pursuant to authority Congress has delegated to the official.

Gonzales, at 258 (citing *United States v Mead Corp.*, 533 U.S. 218, 226-227 (2001) (emphasis added)). See, also, *Ruan v United States*, 142 S.Ct. 2370 (2022) (echoing the *Gonzales* description of the regulatory language and further describing it as “often difficult to distinguish from the gray zone of socially acceptable” conduct and “vague, highly general language”). “Who decides whether a particular activity is in ‘the course of professional practice’ or done for a ‘legitimate medical purpose’” was the “central issue in” *Gonzales v Oregon* and, as the Court concluded, the Attorney General’s regulation “gives little or no instruction” on this central issue. *Gonzales*, at 257. And yet, to this day, the Attorney General has done nothing to clarify the definition of the terms it uses to put doctors and other medical providers in jail.

Those critical terms remain undefined in the law and thus fail to provide practitioners adequate notice. To be sure, various courts have attempted to define those terms, but those definitions vary from circuit to circuit and overstep the authority of Congress to define those terms through the legislative process. No other entity, other than Congress itself, has authority to define the “except as authorized” language of §841(a) nor to define the terms “in the course of professional practice” or “legitimate medical purpose”. -- not HHS, not the CDC, not the FSMB, and certainly not a Government expert through testimony or DOJ Trial Attorney via indictment. If the Attorney General wants to fill the hole and define those terms through clear and succinct

rules, it must comply with the APA in doing so. It may not define those terms through an “expert” by proxy in a court of law and through a criminal proceeding.

Indeed, the Supreme Court has even held that the authority of the Attorney General to make rules regarding controlled substances is extremely limited.

The CSA gives the Attorney General limited powers, to be exercised in specific ways. His rule making authority under the CSA is described in two provisions: (1) "The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals," 21 U.S.C. § 821 (2000 ed., Supp. V); and (2) "The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter," 21 U.S.C. § 871(b). As is evident from these sections, Congress did not delegate to the Attorney General authority to carry out or effect all provisions of the CSA. Rather, **he can promulgate rules relating only to “registration” and “control,” and “for the efficient execution of his functions” under the statute.**

Gonzales, at 259 (emphasis added). Regarding the “control” of drugs, this delegation of authority “cannot sustain the ... attempt to define standards of medical practice.” *Id.*, at 259-260. “The term ‘control’ means to add a drug or other substance, or immediate precursor, to a schedule under part B of this subchapter, whether by transfer from another schedule or otherwise.” *Gonzales*, at 260 (quoting §802(5)). Even if “control” was understood to signify something other than its statutory definition, it would not support the issuance of a vague and ambiguous rule that leaves the door open for a prosecutor to fill in the void with references to outside sources and experts.

The statutory references to “control” outside the scheduling context make clear that the Attorney General can establish controls “against diversion,” e. g., § 823(a)(1), but do not give him authority to define diversion **based on his view of legitimate medical practice.** As explained below, the CSA’s express limitations on the Attorney General’s authority, and other

indications from the statutory scheme, belie any notion that the Attorney General has been granted this implicit authority.

Gonzales, at 260 (emphasis added).

But this is precisely what the Government has done by introducing CDC Guidelines, FSMB Policies, etc. through an expert and the courts, unfortunately, have allowed it – largely because it has not been challenged. It is being challenged here by these practitioners.

The Government (here the prosecutors), as proxies for the Attorney General, have imposed its view of what “legitimate medical practice” should be without Congressional authority and without proceeding through the Administrative Procedures Act. This attempt at defining legitimate medical practice “purports to declare that using controlled substances” in a way that does not conform with FSMB Model Policies or with a Government expert’s opinion of what should be done “is a crime, an authority that goes well beyond the Attorney General’s statutory power to register or deregister.” *Gonzales*, at 261. The problem with using FSMB Model Policies or any other guideline, in part, is that it “cannot, and does not, explain why the Attorney General has the authority to decide what constitutes an underlying violation of the CSA in the first place.” *Gonzales*, at 262. For the Attorney General to use FSMB Guidelines or Model Policies, and even the “training and experience” of a hand-picked, obscure “expert”, is to give him “extraordinary authority.” *Id.* If this is allowed, the Attorney General’s “power to criminalize — unlike his power over registration … would be unrestrained. It would be anomalous for Congress to have so painstakingly described the Attorney General’s limited authority to deregister a single physician or schedule a single drug, but to have given him, just by implication, authority to declare an entire class of activity outside ‘the course of professional practice,’ and therefore a criminal violation of the CSA.” *Gonzales*, at 262.

In sum, the Attorney General was given authority by Congress to implement rules and regulations for the “control” of Controlled Substances (meaning what drugs are listed as controlled substances) and the registration of medical practitioners allowed to prescribe the listed drugs.

Even if this Court presumes that Congress gave the Attorney General authority to define what is a legitimate medical purpose, he has failed to promulgate those definitions via the Administrative Procedures Act. Nor can this Court, or the Sixth Circuit Pattern Jury Instruction Committee, do for the Attorney General what he has failed to do for himself in accordance with clearly established law. For this additional reason, 21 CFR § 1306.04(a) is invalid and cannot be relied upon in prosecuting this case.

VIII. The Attorney General’s regulation (21 CFR § 1306.04(a)) is not entitled to any deference.

The entirety of the Government’s prosecution is premised on the deference given to 21 CFR § 1306.04(a) - an Attorney General regulation defining what an “effective” prescription is and using the terms “legitimate medical purpose”. If the alleged conduct is not in conformance with what the Government says is a legitimate medical purpose, then, according to the Government, it is unlawful and subject to criminal prosecution. This, in effect, is making the “except as authorized” exemption to unlawful conduct in §841(a) *conditional*, based entirely on a regulation. 21 C.F.R. § 1306.04 is not only given immense deference by the courts, but it is the essential foundation for all these prosecutions of medical providers. Even the Sixth Circuit Pattern Jury Instruction Committee picked up on the regulation as the foundation for listing the elements of the offense.¹⁸ And the Government explicitly relies on the regulation when alleging

¹⁸ “The defendant’s dispensing was unauthorized, that is to say the dispensing was

that the defendants' conduct was "not legal". (D.E. 40, Superseding Indictment ¶5).

Chevron deference, which has existed for many decades, is forecasted to be on the brink of extinction. Cornell Law School published an excellent summary of "*Chevron* deference":

One of the most important principles in administrative law, the "*Chevron* deference" was coined after a landmark case, *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 468 U.S. 837 (1984). The *Chevron* deference is referring to the doctrine of judicial deference given to administrative actions. In *Chevron*, the Supreme Court set forth a legal test as to when the court should defer to the agency's answer or interpretation, holding that such judicial deference is appropriate where the agency's answer was not unreasonable, so long as Congress had not spoken directly to the precise issue at question.

The scope of the *Chevron* deference doctrine is that when a legislative delegation to an administrative agency on a particular issue or question is not explicit but rather implicit, a court may not substitute its own interpretation of the statute for a reasonable interpretation made by the administrative agency. Rather, as Justice Stevens wrote in *Chevron*, when the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's action was based on a permissible construction of the statute.

First, the *Chevron* deference requires that the administrative interpretation in question was issued by the agency charged with administering that statute. Accordingly, **interpretations by agencies not in charge of the statute in question are not owed any judicial deference**. Also, the implicit delegation of authority to an administrative agency to interpret a statute does not extend to the agency's interpretation of its own jurisdiction under that statute.

Generally, to be accorded *Chevron* deference, the agency's interpretation of an ambiguous statute must be permissible, which the court has defined to mean "rational" or "reasonable." In determining the reasonableness for the particular construction of a statute by the agency, the age of that administrative interpretation as well as the congressional action or inaction in response to that

not for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice". (6th Circuit PJI 14.02C).

interpretation at issue can be a useful guide; if Congress was aware of the interpretation when it acted or refrained from action, and when the agency's interpretation is not inconsistent with the clear statutory language.

In subsequent cases, the Supreme Court has narrowed the scope of Chevron deference, holding that **only the agency interpretations reached through formal proceedings with the force of law, such as adjudications, or notice-and-comment rulemaking, qualify for Chevron deference**, while those contained in opinion letters, policy statements, agency manuals, **or other formats that do not carry the force of law are not warranted a Chevron deference**. In such cases, the Court may give a slightly less deferential treatment to the agency's interpretation, giving a persuasive value under the Court's "Skidmore deference" analysis.

(See, https://www.law.cornell.edu/wex/chevron_deference, last visited March 10, 2024)

(emphasis added).¹⁹

Years later, the Supreme Court used "*Chevron* deference" to resolve a question of an agency's interpretation of its own rules. *Chevron*, in contrast, involved an agency's interpretation of an enabling statute giving that agency authority to promulgate regulations. In *Auer v. Robbins*, 519 U.S. 452 (1997), the Supreme Court considered the standard to use when a court reviews an executive department's interpretation of its own regulations. Under *Auer*, an agency's interpretation of its own regulation is "controlling unless 'plainly erroneous or inconsistent with the regulation.'" *Auer*, at 461. This is so even if that interpretation comes about through a process other than the APA, such as in the "form of a legal brief". *Id.*, at 462.

Between the two cases, the doctrine is sometimes referred to jointly as the *Chevron/Auer* deference doctrine. Legal scholars have bemoaned the broad powers that *Chevron/Auer* gives to

¹⁹ Cornell Law School's Wex Definitions Team is a group of Cornell Law Students organized and supervised by LII Original Content Collections Manager Nichole McCarthy to provide enhanced definitions of important legal terms and concepts to aid the general public in understanding them.

federal agencies. Because of *Auer*, federal agencies may be inclined to write vague regulations so that they can be interpreted later during legal proceedings. See, Manning, John, “Constitutional Structure and Judicial Deference to Agency Interpretations of Agency Rules”, 96 Colum. L. Rev. 612 (1996) (With the deference cases “the agency effectively secures the power of self-interpretation. This authority permits an agency to fill in regulatory gaps or ambiguities of its own making and relieves the agency of the cost of imprecision that it has produced. This state of affairs makes it that much less likely that an agency will give clear notice of its policies either to those who participate in the rulemaking process prescribed by the Administrative Procedure Act (APA) or to the regulated public.”) See also, Herz, Michael, “Symposium: In ‘Gundy II,’ *Auer* survives by a vote of 4.6 to 4.4”, Scotusblog, June 27, 2019,

<https://www.scotusblog.com/2019/06/symposium-in-gundy-ii-auer-survives-by-a-vote-of-4-6-to-4-4/> (last visited March 8, 2024) (“*Auer* deference creates terrible incentives for agencies, who will promulgate intentionally vague regulations through notice and comment, and then make their real decisions later via ‘interpretations,’ effectively free of public input or judicial scrutiny.)²⁰ As Professor Herz succinctly noted, “[t]he ensuing years saw some additional shots in concurring opinions by Scalia and others as well as modest chipping away in majority opinions (no *Auer* deference for interpretations of regulations that simply parrot statutory language; no *Auer* deference for interpretations that could not have been foreseen and upset strong reliance interests).” *Id.*

In 2019, the U.S. Supreme Court revisited *Auer* and, without directly overturning it, as the petitioner had advocated, the doctrine was weakened. *Kisor v Wilkie*, 139 S.Ct. 2400 (2019).

²⁰ John F. Manning is a Professor at Harvard Law School. Michael Herz is the Arthur Kaplan Professor of Law at Benjamin N. Cardozo School of Law, Yeshiva University.

As Justice Kagan wrote for the majority, “*Auer* deference is sometimes appropriate and sometimes not. Whether to apply it depends on a range of considerations that we have noted now and again, but compile and further develop today.” The Court explained that *Auer* deference would not be warranted “when a court concludes that an interpretation does not reflect an agency’s authoritative, expertise-based, fair[, or] considered judgment.” *Kisor*, at 2414 (internal quotations omitted).

First and foremost, a court should not afford *Auer* deference unless the regulation is genuinely ambiguous. ... And before concluding that a rule is genuinely ambiguous, a court must exhaust all the ‘traditional tools’ of construction. ... If genuine ambiguity remains, moreover, the agency’s reading must still be ‘reasonable.’ ... In other words, it must come within the zone of ambiguity the court has identified after employing all its interpretive tools.

Id., at 2416-17 (internal citations omitted). Moreover, the “basis for deference ebbs when ‘[t]he subject matter of the [dispute is] distant from the agency’s ordinary’ duties or ‘fall[s] within the scope of another agency’s authority.’” *Id.*, at 2417.

Despite these clarifications of the scope of *Auer* deference, four justices dissented, arguing that it “should have been easy for the Court to say goodbye to *Auer v Robbins*.” *Kisor*, at 2425 (J. Gorsuch, dissenting, joined by J. Thomas, J. Kavanaugh, and J. Alito).²¹ The dissent noted that *Auer* deference was “invented” by the Court

almost by accident and without any meaningful effort to reconcile it with the Administrative Procedure Act or the Constitution. A legion of academics, lower court judges, and Members of this Court — even *Auer*’s author [J. Scalia] — has called on us to abandon *Auer*. Yet today a bare majority flinches, and *Auer* lives on.

²¹ Two of the justices on the majority, J. Ginsburg and J. Breyer, are no longer on the bench, and given the dissent that Chief Justice Roberts joined in *Gundy*, it appears the votes are there to overturn *Chevron*.

Id.

Since *Kisor*, other cases have sounded the bugle. *Baldwin v. United States*, 140 S. Ct. 690 (2020) (Thomas, J., concurring) (“*Chevron* also gives federal agencies unconstitutional power”); *Michigan v. EPA*, 135 S. Ct. 2699, 2715 (2015) (Thomas, J., concurring) (“*Chevron* deference raises serious separation-of-powers questions”); *Buffington v. McDonough*, 143 S. Ct. 14, 18–19 (2022) (Gorsuch, J., dissenting) (criticizing *Chevron* in stating that “[r]ather than provide individuals with the best understanding of their rights and duties under law a neutral magistrate can muster, we outsource our interpretive responsibilities. Rather than say what the law is, we tell those who come before us to go ask a bureaucrat.”). The bell is clearly tolling for *Chevron/Auer* deference.

On May 1, 2023, in *Loper Bright Enterprises et al. v. Gina Raimondo et al.*, No. 22-451, the Supreme Court granted *certiorari* for some commercial fishing companies who claimed that the National Marine Fisheries Service lacked authority to require them to pay to carry observers aboard their ships to ensure compliance with federal regulations. The question presented is, “Whether the court should overrule *Chevron* or at least clarify that statutory silence concerning controversial powers expressly but narrowly granted elsewhere in the statute does not constitute an ambiguity requiring deference to the agency.” The four justices who penned the dissent in *Kisor* seem eager to overturn *Chevron/Auer*. Only one more justice is needed to end *Chevron/Auer* deference, and the oral argument seems to suggest the votes exist.

In what might be called an anti-administrative authority trend, the Supreme Court has been hinting at limiting the authority of federal agencies in almost every context. Take the case of *West Virginia v Environmental Protection Agency*, 142 S.Ct. 2587 (2022), decided on June 30, 2022, with the majority opinion written by Justice Roberts. There, the Supreme Court

considered whether the EPA had authority to regulate certain pollutants from existing sources under the Clean Air Act, 42 U.S.C. §7411. The main holding of *West Virginia v EPA* is this:

Where the statute at issue is one that confers authority upon an administrative agency, that inquiry must be “shaped, at least in some measure, by the nature of the question presented”—whether Congress in fact meant to confer the power the agency has asserted.

West Virginia v EPA, at 2607-08.²² “Agencies have only those powers given to them by Congress, and ‘enabling legislation’ is generally not an ‘open book to which the agency [may] add pages and change the plot line.’” *Id.*, at 2609 (Quoting E. Gellhorn & P. Verkuil, *Controlling Chevron-Based Delegations*, 20 Cardozo L. Rev. 989, 1011 (1999)). An agency “must point to clear congressional authorization for the power it claims.” *Id.* (internal quotation marks omitted). “Extraordinary grants of regulatory authority are rarely accomplished through ‘modest words,’ ‘vague terms,’ or ‘subtle device[s].’ Nor does Congress typically use oblique or elliptical language to empower an agency to make a ‘radical or fundamental change’ to a statutory scheme.” *Id.* (internal citations omitted).

Again, in *Alabama Association of Realtors v HHS*, 141 S.Ct. 2485 (2021), decided on August 26, 2021, the Supreme Court continued its attack on agency power. There, the Centers for Disease Control (CDC) had imposed a nationwide moratorium on evictions of any tenants who lived in a county that had experienced high levels of Covid-19 transmission and who were in financial distress. In support of that action, the CDC invoked a decades-old statute that authorized it to create measures like fumigation and pest control. The Supreme Court struck

²² In the context of the instant case, the question presented is, did Congress in fact mean to confer to the Attorney General the power to *condition* the “as authorized” exception in §841(a) on the extra-regulatory opinion of what constitutes “legitimate medical purpose” and to criminalize conduct that did not conform to that opinion.

down the moratorium because the statute did not grant the CDC such sweeping authority.

The statute relied on by the CDC gave the Surgeon General, with the approval of HHS, the authority to “make and enforce regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.” In order to carry out and enforce such regulations, the statute gave the Surgeon General (who delegated the role to the CDC) the power to perform certain functions “as in his judgment may be necessary.” 42 U.S.C. §264(a). The Government argued that the first sentence gave the CDC broad authority to take whatever measures it deemed necessary to control the spread of COVID-19, including issuing a moratorium on evictions. The Court rejected that reading, though, and noted that the second part “inform[ed] the grant of authority by illustrating the kinds of measures that could be necessary”. *Alabama Realtors*, at 2488. The moratorium, however, related to infections indirectly by a “downstream connection between eviction and interstate spread of disease”. *Id.* The two sentences had to be read together rather than in isolation and doing so made the CDC’s authority to impose a moratorium a “stretch”. *Id.*, at 2489. “Even if the text were ambiguous, the sheer scope of the CDC’s claimed authority … would counsel against the Government’s interpretation. We expect Congress to speak clearly when authorizing an agency to exercise powers of ‘vast economic and political significance.’” *Id.* (Internal quotation marks omitted). “And the issues at stake are not merely financial. The moratorium intrudes into an area that is the particular domain of state law: the landlord-tenant relationship. Our precedents require Congress to enact exceedingly clear language if it wishes to significantly alter the balance between federal and state power and the power of the Government over private property.” *Id.*, at

2489 (internal quotation marks and citations omitted).

In *Biden v Nebraska*, 143 S.Ct. 2355 (2023), the Court considered the issue of “whether the Secretary [of Education] has authority under the Higher Education Relief Opportunities for Students Act of 2003 (HEROES Act) to depart from the existing provisions of the Education Act and establish a student loan forgiveness program that will cancel about \$430 billion in debt principal and affect nearly all borrowers.” *Biden*, at 2355 (Syllabus). The Court held that the HEROES Act allowed the Secretary to “waive or modify” existing statutory or regulatory provisions applicable to financial assistance programs under the Education Act but did not allow the Secretary to rewrite that statute to the extent of canceling \$430 billion of student loan principal. According to the Supreme Court, just because the Act gave the Secretary authority to “modify” loans did not give him the authority to make “basic and fundamental changes in the scheme designed by Congress.” *Id.*, at 2368 (internal quotation marks omitted). “The Secretary’s plan has ‘modified’ the cited provisions only in the same sense that the French Revolution ‘modified’ the status of the French nobility — it has abolished them and supplanted them with a new regime entirely.” (*Id.*, at 2369, internal quotation marks omitted).

In the case *sub judice*, the entirety of the Government’s purported authority to criminally prosecute medical practitioners even though they were registered and therefore “authorized” under §841(a) is founded on the Attorney General’s regulation, 21 C.F.R. § 1306.04, and the use of the term “legitimate medical purpose.” Although that term is not further defined in the CFR, the Government uses guidelines issued by other agencies to define what is “legitimate” medical practice. Courts have routinely deferred to this construct using *Auer* deference. In other words, the Attorney General promulgated § 1306.04 and parroted the “legitimate medical purpose” language of the CFR, leaving that term ambiguous, exactly as legal scholars warned would

happen. Then the Attorney General, through the criminal prosecution process and outside the structure of the APA, defined “legitimate medical purpose” as the standard of care in a state, the nation, or within a particular medical field through the use of experts and guidelines issued by other agencies. And the Courts have gone along. “[T]he Attorney General's interpretation of ‘legitimate medical purpose’ in 21 CFR § 1306.04 (2005) (hereinafter Regulation) is clearly valid, given the substantial deference we must accord it under *Auer v. Robbins*, 519 U.S. 452, 461 (1997)...” *Gonzales v Oregon*, 546 U.S. 243 (2006) (J. Scalia dissenting).²³ If *Chevron/Auer* deference is overturned or even weakened even more, which surely seems the way the Supreme Court is headed, then the entire basis for deferring to the Attorney General's interpretation of the Controlled Substances Act, his authority to *condition* the “as authorized” exception in §841(a), and his use of the criminal process to further interpret what “legitimate medical purpose” means outside the process of the Administrative Procedures Act, will be thrown in the ash heap of overturned laws.

Like *West Virginia v EPA*, the Attorney General is using his limited regulatory authority to make radical and fundamental changes to the Controlled Substances Act. Congress gave clear direction that his limited authority was to administer the registration of those applying for permission to distribute or dispense controlled substances and to move those substances from one schedule to another. Congress also provided an administrative scheme to suspend or revoke such registration provided the Attorney General found certain enumerated conditions. Congress did *not*, however, explicitly or implicitly confer on the Attorney General the power to place *conditions* on the term “authorized”, as used in §841(a), upon meeting a vague and oblique

²³ Remember, though, that J. Scalia later lamented his reliance on *Auer*. See, discussion *supra*.

condition such as the medical purpose being “legitimate”. It certainly did not confer on the Attorney General the power to delegate the definition of what is a “legitimate medical purpose” to some guideline issued by another agency or private entity or to an opinion by a Government expert.

While *West Virginia v EPA* was decided, in part, on the introduction of the “major questions doctrine” in the context of the “national economy”, the ruling made clear that it was the result of a **“recurring problem: agencies asserting highly consequential power beyond what Congress could reasonably be understood to have granted.”** (*Id.*, at 2609, emphasis added). There can be no rationale debate that the Attorney General putting physicians and other medical providers in prison as drug dealers for prescribing controlled substances when not in conformance with a vague and ill-defined term like “legitimate medical purpose” and when Congress never gave him the authority to do so is a “highly consequential power”. Indeed, these efforts by the Government to imprison doctors and others, especially those in rural areas, has sent shock waves throughout the medical profession and medical practitioners are afraid to prescribe pain-killing opioids to patients in severe pain out of fear of being prosecuted. With so many different so-called guidelines on opioid prescribing – CDC Guidelines, FSMB Guidelines, FSMB Model Policies, State Medical Board regulations, Journal articles, etc., medical providers are left without consistent and reliable guidance. If this does not invoke the “major questions doctrine”, then that doctrine has no real teeth.

Like the EPA over-regulating pollutants or the CDC improperly prohibiting evictions on the pretense of controlling infections, the Controlled Substances Act simply does not give the Attorney General the authority to prosecute medical providers who are “authorized” to dispense controlled substances through the registration process created by the CSA based on what the

Government contends is “legitimate” medical practice. The practice of medicine across the United States, and particularly the practice of controlling pain, has an enormous impact on the economy.

The health-care sector is in many ways the most consequential part of the United States economy. It is a fundamental part of people’s lives, supporting their health and well-being. Moreover, it matters because of its economic size and budgetary implications. The health-care sector now employs 11 percent of American workers (Bureau of Labor Statistics [BLS] 1980–2019b and authors’ calculations) and accounts for 24 percent of government spending (Centers for Medicare & Medicaid Services [CMS] 1987–2018; Bureau of Economic Analysis 1987–2018; authors’ calculations). Health insurance is the largest component (26 percent) of nonwage compensation (BLS 2019b) and health care is one of the largest categories of consumer spending (8.1 percent of consumer expenditures; BLS 2019a).

Junn, Ryan, et al., “A Dozen Facts about the Economics of the U.S. Health-Care System”, Economic Facts, March 2020 (found at <https://www.brookings.edu/articles/a-dozen-facts-about-the-economics-of-the-u-s-health-care-system/> (last visited March 5, 2024). Also, the Attorney General dictating what “legitimate” medical practice is with the threat of incarceration intrudes into an area that is the particular domain of state law: the practice of medicine. If Congress had wanted to significantly alter the balance between federal and state power and the power of the Government over the practice of medicine, it should have enacted exceedingly clear language granting to the Attorney General the power to do so.

Like in *Biden v Nebraska*, the Attorney General has made fundamental changes to the “scheme” created by Congress to register prescribers of controlled substances. He has changed the administrative scheme to register and then suspend or revoke that registration upon finding very specific factors by creating a harsher scheme of putting medical providers in prison for violating a *condition* he created to being “authorized”. Yet, Congress never gave him the

authority to *condition* the “as authorized” term upon meeting a vague notion of “legitimate” medical practice based on confusing, contradictory, and vague guidelines and selected Government experts. The Attorney General’s scheme of prosecuting medical providers instead of following the administrative procedure outlined in the CSA drastically changed the scheme created by Congress.

In January 2024, the United States Supreme Court heard nearly four hours of oral arguments in the combined cases of *Relentless, Inc. v. Department of Commerce*, Case No. 22-1219 and *Loper Bright Enterprises v. Raimondo*, Case No. 22-451.²⁴ Every major publication and scholar forecasts that the United States Supreme Court will overturn *Chevron* deference. Without the ability to rely on *Chevron* deference, the Government is utterly devoid of any authority to interpret statutory meaning for 21 U.S.C. §841(a). Without *Auer* deference, the Government is equally devoid of any authority to interpret its own vague regulations. While the defense insists that the Government cannot expand Congress’ stated intentions with its CFRs, if *Chevron/Auer* is reversed, the Government is stripped of any responsive arguments.

The U.S. Supreme Court’s looming ruling in *Chevron/Auer* may have a direct impact on this motion since, if the Court reverses *Chevron/Auer*, the DOJ will lose any power it may have to interpret 21 U.S.C. §841(a) or its own regulation, 21 U.S.C. § 1306.04.²⁵ This issue will be decided by the end of its term (on or before June 30, 2024.).

IX. Conclusion

For the reasons stated herein, the Defendants’ motion to dismiss the superseding indictment for lack of subject matter jurisdiction should be granted.

²⁴ In *Relentless*, the direct question presented is, “whether this Court should overrule or clarify the *Chevron* doctrine.” (Brief for Petitioners).

Respectfully submitted,

HODDE & ASSOCIATES
40 Music Square East
Nashville, TN 37203
(615) 242-4200

BY: /s/ Kimberly S. Hodde
KIMBERLY S. HODDE
Attorney for Defendant Hemal Mehta, M.D.

MEGGAN BESS SULLIVAN
424 Church Street
Suite 2000
Nashville, TN 37219
(615) 457-0449
msullivan@chapmanlawgroup.com

BY: /s/ Meggan Bess Sullivan
MEGGAN BLESS SULLIVAN
Attorney for Heather Marks, N.P.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing has been sent via the Court's electronic filing system, *or*, if not registered, sent U.S. Mail, postage prepaid, to:

Leslie Fisher
DOJ Trial Attorney
719 Church Street
Suite 3300
Nashville, TN 37203

this 10th day of March, 2024.

/s/ Kimberly S. Hodde
KIMBERLY S. HODDE

25 In addition to the lack of authority from the plain text of the CSA.